### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/663,506 Confirmation No.: 1850

Applicant : Ashraf et al.

Filed: September 15, 2003

TC/A.U. : 1627

Examiner : Carter, Kendra D

Customer No.: 38199

Title : SOLID ORAL FORMULATIONS OF RAPAMYCIN 42-ESTER

WITH 3-HYDROXY-2-(HYDROXYMETHYL)-2-

METHYLPROPIONIC ACID

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## THIRD INFORMATION DISCLOSURE STATEMENT

Sir:

Applicant(s) submit(s) to the Examiner the attached document listing and this
paper pursuant to 37 CFR §§1.56 and 1.97-1.98. The:

	form(s) is/are	
$\boxtimes$	form(s) and document(s) is/are	
attached.		

This Information Disclosure Statement is submitted:

less than three months from the filing of a Request for Continued Examination. Therefore, no fees are believed due.

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more than three months from the filing date of this application and before
the receipt of a first Office Action on the merits. Therefore, no fees are
believed due.
less than three months from the filing date of this application, but after the
receipt of a first Office Action on the merits. However, no fees are
believed due.
more than three months from the filing date of this application and after
the receipt of a first Office Action on the merits. Therefore, the fee of
\$180 is believed due and the Director is hereby authorized to charge the
fee of \$180 to our Deposit Account Number 08-3040.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

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#### REMARKS

The following information is provided in accordance with the requirement of 37 CFR §§1.97-1.98. In the event that the Examiner considers the inclusion of this/these item(s) on the attached form(s) inappropriate and strikes out the citation on the form(s), Applicant(s) request(s) that the Examiner indicate consideration of the attached document(s) in the body of the next paper, *i.e.*, Office Action or Notice of Allowability. Because this information disclosure statement (IDS) is in accordance with the provisions of 37 CFR §§1.97-1.98, consideration of this/these document(s) by the Examiner is required (See MPEP §609).

# OFFICE ACTIONS ISSUED BY FOREIGN PATENT OFFICES

In an effort to submit information for consideration by the USPTO, Applicant(s) submit(s) the following:

1. Office Action dated February 9, 2010 and issued in counterpart Japanese Patent Application No.2004-537911.

Official Office Action?	English Translation of Office Action?	Correspondence from Agent regarding Office Action*	Response to Office Action Attached
☐ Yes ⊠ No	<ul><li></li></ul>	Yes No N/A	Yes No

<sup>\*</sup> confidential information redacted from correspondence.

Pursuant to 37 CFR §1.98(a)(1), this/these item(s) is/are included on the attached form entitled "Other information submitted for consideration by the Office". The attached are/is submitted solely in an effort to ensure that the Examiner has an opportunity to consider information that was considered by a foreign patent office(s). However, Applicant(s) maintain(s) that the mere submission of this/these document(s) is

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not an admission that the same is material to patentability (See MPEP §609). Also provided is/are the official Response(s) thereto, where applicable.

### DOCUMENTS IN A FOREIGN LANGUAGE

Document "EE" is an English-language translation of page 344, right column, line 20 to page 345, left column, line 10, of a foreign language dictionary of pharmaceutical additives. The section ("antioxidants") is combined with Document "DD" and allegedly teaches that "it is conventional to add known additives such as butylated hydroxytoluene [] in order to enhance stability of a preparation."

### MONTHS OF PUBLICATION

The month of publication for document EE could not be determined. The year of publication for this document is sufficiently earlier than the effective US filing date and/or the foreign priority date of the present application so that the particular month of publication of the document(s) is not in issue (MPEP §609).

The Examiner is respectfully requested to consider the document(s) identified in this paper and in the attached form(s) during the course of examination of this application.

Respectfully submitted,

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